REFERENCES

1. Kini V, Soufi MK, Deo R, et al. Appropriateness of primary prevention implantable cardioverter-defibrillators at the time of generator replacement: are indications still met? J Am Coll Cardiol 2014;63:2388–94.

2. Myerburg RJ, Castellanos A. Cardiac arrest and sudden death. In: Braunwald E, editor. Heart disease: a textbook of cardiovascular medicine. Philadelphia: WB Saunders, 1997:742–79.

3. Klem I, Weinsaft JW, Bahnson TD, et al. Assessment of myocardial scarring improves risk stratification in patients evaluated for cardiac defibrillator implantation. J Am Coll Cardiol 2012;60:408–20.

REPLY: Ejection Fraction May Improve But the Scar Still Exists! The Risk May Be Lower But Not Zero

We thank Dr. Pillarisetti and colleagues for their interest in our report (1). However, we disagree with the conclusions they have drawn from additional analysis of our data. They argue that patients with primary prevention implantable cardioverter-defibrillators (ICDs) who experience no appropriate ICD therapy and demonstrate improvement of left ventricular ejection fraction (LVEF) to ≥40% should routinely undergo generator replacement (GR). To further this argument, they have analyzed the event rate (appropriate ICD therapy) of 2.8% per person-year that we observed in the group of patients who underwent GR despite improved LVEF and have derived a number needed to treat (NNT) of 76 to prevent 1 appropriate ICD therapy. They further contend that the NNT may have been lower if patients who experienced appropriate ICD therapy despite improvement in LVEF before GR were included. However, their latter contention is invalid because in our study these patients fulfilled secondary prevention indications for ICD therapy. This point notwithstanding, is an NNT of 76 to prevent 1 appropriate ICD therapy sufficient to justify routine GR?

In the largest trial assessing efficacy of primary prevention ICD therapy, i.e., SCD-HeFT (Sudden Cardiac Death in Heart Failure Trial) (2), the NNT with ICD to prevent 1 death was 20. Similar NNTs have been shown for other lifesaving advances in cardiology that have gained widespread acceptance. For example, the NNT with primary coronary angioplasty (versus thrombolytic therapy) to prevent 1 death from acute myocardial infarction is 10 (3), and the NNT with beta-blockers in chronic heart failure to prevent 1 death is 15 (4). While it is unclear (and subjective) what an "acceptable" NNT should be for GR in recipients of primary prevention ICD, an NNT of 76 to prevent 1 appropriate device therapy (which is not synonymous with mortality) is clearly much higher than what has been shown with other lifesaving cardiovascular therapies. Furthermore, the potential risks of the GR procedure must be taken into account. Data from the REPLACE (Implantable Cardiac Pulse Generator Replacement) registry show that the major complication rate for patients undergoing ICD GR is 5% (5). This would imply that for 1 patient to receive appropriate ICD therapy after GR, 4 patients would experience a major complication from the procedure.

The principle of nonmaleficence necessitates weighing any lifesaving benefit against the potential for harm. The latter in patients undergoing ICD GR includes inappropriate shocks, pocket or device infections, device malfunction, and manufacturer recalls. Why an approach of LVEF reassessment and informed discussion regarding the uncertain benefits and risks of GR in this patient population, as suggested by our study, is perceived as "bold and sweeping" by Dr. Pillarisetti and colleagues remains unclear to us. In any situation in which there is significant uncertainty regarding the benefits of a treatment, deferring to patient preference after sharing all the relevant information without bias is, in our opinion, the optimal approach.

Vinay Kini, MD
***Sanjay Dixit, MD**
*9 Founders
Hospital of the University of Pennsylvania
3400 Spruce Street
Philadelphia, Pennsylvania 19104
E-mail: sanjay.dixit@uphs.upenn.edu

http://dx.doi.org/10.1016/j.jacc.2014.06.1164

Please note: Dr. Dixit has received a research grant from Medtronic and fellowship support from Boston Scientific, Medtronic, and St. Jude Medical. Dr. Kini has reported that he has no relationships relevant to the contents of this paper to disclose.

REFERENCES

1. Kini V, Soufi MK, Deo R, et al. Appropriateness of primary prevention implantable cardioverter-defibrillators at the time of generator replacement: are indications still met? J Am Coll Cardiol 2014;63:2388–94.

2. Bardy GH, Lee KL, Mark DB, et al. Amiodarone or an implantable cardioverter-defibrillator for congestive heart failure (SCD-HeFT). N Engl J Med 2005;352:225–37.

3. Zijlstra F, Jan de Boer M, Hoorntje J, et al. A comparison of immediate coronary angioplasty with intravenous streptokinase in acute myocardial infarction. N Engl J Med 1993;328:680–4.

4. Chatterjee S, Biondi-Zoccai G, Abbate A, et al. Benefits of beta blockers in patients with heart failure and reduced ejection fraction: network meta-analysis. BMJ 2013;346:f55.

5. Poole JE, Gleva MJ, Mela T, et al. Complication rates associated with pacemaker or implantable cardioverter-defibrillator generator replacements and upgrade procedures: results from the REPLACE registry. Circulation 2010; 122:1553–61.